IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
EASTERN DIVISION

SANTURCE PHARMACEUTICAL CORP. PLAINTIFF

VS. CIVIL ACTION NO. 1:04CV254-D-A

SECRETARY OF HEALTH
AND HUMAN SERVICES DEFENDANT

REPORT AND RECOMMENDATION

This case involves an application pursuant to 42 U.S.C 1395ff (b)(1)(a) for judicial review of a final decision of the Secretary of the Department of Health and Human Services. The parties have not consented to have a magistrate judge conduct all the proceedings in this case; therefore, the undersigned submits this report and recommendation to the United States District Judge. The undersigned has reviewed the motions and the record int his case and finds as follows.

I. FACTUAL AND PROCEDURAL HISTORY

The plaintiff, a supplier of durable medical equipment ("DME") submitted claims for reimbursement to Medicare. The Secretary denied these claims for lack of adequate documentation demonstrating that the items furnished were medically necessary, a prerequisite for medicare reimbursement. Plaintiff's claims were denied at all stages of administrative review for failure to submit such documentation. Following a hearing, on February 17, 2004, the Administrative Law Judge ("ALJ") entered a decision that plaintiff was not entitled to reimbursement for certain claims. On June 21, 2004, the Medicare Appeals Council denied the plaintiff's request for review, finding no abuse of discretion or error of law and that the ALJ's decision was supported by substantial evidence. Thereafter, the plaintiff filed the present action

with this court. Before the court are cross-motions for summary judgment. The ALJ's final hearing decision is now ripe for review.

The plaintiff claimed that it was entitled to reimbursement of Medicare costs under Part B of the Medicare Act, which provides for optional coverage of outpatient care. 42 U.S.C. § 1395j-1395w. Part B provides for coverage of DME ("durable medical equipment"), and plaintiff is a supplier of DME. 42 C.F.R. Section 400.200. In administering Part B, the Centers for Medicare and Medicaid Services ("CMS"), act through private fiscal agents called "carriers." 42 U.S.C. § 1395u; 42 C.F.R. Part 421, Subparts A and C, and 42 C.F.R. § 421.5(b). The carriers are private entities that contract with the Secretary to perform different functions, including but not limited to making coverage determinations in accordance with the Medicare Act, determining reimbursement rates and allowable payments, conducting audits of the claims submitted for payment, and rejecting or adjusting payment requests. 42 U.S.C. § 1395u(b)(3) (B); 42 C.F.R. § 421.200.

In determining reimbursement costs for DME, the supplier must demonstrate that the items it supplies are medically necessary. Further, to prevent fraud or abuse of funds distributed through the Medicare Act, the carriers can identify claims for additional development, in which case supplemental documents are required to prove medical necessity. The additional document requirements are explained in Medicare Advisories, readily available to the supplier.

On appeal to this court the plaintiff makes the following arguments: (1) the wrong legal standards were applied; and (2) the decision is contrary to the overwhelming weight of the law and evidence. The court will address the plaintiff's arguments.

II. STANDARD OF REVIEW

Before the court are cross-motions for summary judgment. When cross-motions for summary judgment are made, as here, the standard is the same as that for individual motions for summary judgment. Each motion must be considered independently of the other and, when evaluating each, the court must consider the facts in light most favorable to the non-moving party. *Hemblin, Inc. v. United States*, 996 F.2d 1455, 1461 (2d Cir. 1993). Where the record, taken as a whole, could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 587 (1986); *Federal Savings and Loan, Inc. v. Krajl*, 968 F.2d 500 (5th Cir. 1992). The facts are reviewed drawing all reasonable inferences in favor of the non-moving party. *Matagorda County v. Russel Law*, 19 F.3d 215, 217 (5th Cir. 1994).

This court's review of the Secretary's decision is limited to an inquiry into whether there is substantial evidence to support the findings of the Secretary, *Richardson v. Perales*, 402 U.S. 389, 401 (1971), and whether the correct legal standards were applied. 42 U.S.C. § 405(g); *Falco v. Shalala*, 27 F.3d 160, 163 (5th Cir. 1994); *Villa v. Sullivan*, 895 F.2d 1019, 1021 (5th Cir. 1990). Substantial evidence has been defined as "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Perales*, 402 U.S. at 401 (quoting *Consolidated Edison v. NLRB*, 305 U.S. 197, 229 (1938)). Further, in Medicare reimbursement review cases, where 405(g) governs the standard of review, *Frith v. Celebrezze*, 333 F.2d 557, 560 (5th Cir. 1964), the Fifth Circuit has held that appellate review is limited to two issues: (1) whether the proper legal standards were applied; and (2) whether the decision is supported by substantial evidence on the record as a whole. *Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2001) citing *Paul v. Shalala*, 29 F.3d 208, 210 (5th Cir.

1994); *Anthony v. Sullivan*, 954 F.2d 289, 292 (5th Cir. 1992). This court may not overturn the Secretary's decision if it is supported by substantial evidence, that is, "more than a mere scintilla," and correctly applies the law. *Morris* at 745; *Anthony* at 292.

Conflicts in the evidence are for the Secretary to decide, and if substantial evidence is found to support the decision, the decision must be affirmed even if there is evidence on the other side. *Selders v. Sullivan*, 914 F.2d 614, 617 (5th Cir. 1990). The court may not re-weigh the evidence, try the case de novo, or substitute its own judgment for that of the Secretary , even if it finds that the evidence preponderates against the Secretary's decision. *Hollis v. Bowen*, 837 F.2d 1378, 1383 (5th Cir. 1988); *Bowling v. Shalala*, 36 F.3d 431, 434 (5th Cir. 1994); *Harrell*, 862 F.2d at 475. If the Secretary's decision is supported by the evidence, then it is conclusive and must be upheld. *Paul v. Shalala*, 29 F.3d 208, 210 (5th Cir. 1994).

III. DISCUSSION

A. Application of Proper Legal Standards

The plaintiff's first argument is that the ALJ did not apply the proper legal standards. In furthering this argument, the plaintiff makes two specific assignments of error: 1) that the ALJ required more documentation from the plaintiff than necessary under the law, and 2) that the ALJ held plaintiff to a higher standard than prescribed by the law. To the extent that the plaintiff argues that the ALJ generally misapplied legal standards regarding the medical documentation required the court addresses this argument below.

1. Requirement of adequate documentation to prove medical necessity

The fact that the ALJ found that the plaintiff had not produced adequate documentation to justify reimbursement of costs is completely within the discretion of the ALJ. Plaintiff argues that "Santurce simply had the option of submitting physician notes or other

documentation to meet its medical records submission requirement." (Brief of Plaintiff, p. 6) In fact, there was no such option. Rather, the plaintiff, as a supplier of DME, is required to follow very precise and detailed guidelines as provided in administrative manuals, produced by regional carriers, who act under the authority of the Secretary. 42 U.S.C.§ 1395u; 42 C.F.R. Part 421, Subparts A and C, and 42 C.F.R.§ 421.5 (b). The plaintiff correctly identifies the requirements for claims submitted by suppliers, as provided by the Region C DMERC Supplier Manual: (1) physician order for the services billed; (2) delivery ticket; and (3) medical records to corroborate the order. These requirements do not apply, however, to the claims at issue. The ALJ correctly held that plaintiff was subject to, and failed to comply with, supplemental documentation requirements. (T. 55)

The regional carrier, responsible for handling the claims relevant to this case, detected an overutilization of claims for nebulizers, and all claims were under review. The claims in this case had been selected for additional development, and in such a case more specific documents are required to prove medical necessity. (T. 55-56;751, 763). The additional documentation requirements are found in the Medicare Advisories (T. 751). A review by this court of the Medicare Advisory reflects an effort by the carriers, who publish the manuals, to highlight the different, and more specific, requirements mandated for an additional development claim. In the Spring 2001 DMERC Medicare Advisory, (id.), the heading "**Additional Development Requests for DMERC Medical Review**" is highlighted by all capital letters and bold type. (Id.) On the same page, below and to the right of the aforementioned heading, again in all capital letters, the manual reads, "Important Information for responding to an additional development request for medical records." (Id.). Clearly, the carriers' intent was to distinguish the document requirements for an additional development claim from those of a standard claim.

Further, the Spring 2001 DMERC Medicare Advisory, (T. 751), provided the documentation requirements for an additional development:

(1) Orders for services rendered (Orders must be detailed and signed and dated by the treating physician)
(2) Certificate of Medical Necessity (if applicable)
(3) Clinical information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable). It may also include information on a supplier-prepared statement or physician attestation. (if applicable).
(4) Product information, manufacturer, brand name, model, etc.
(5) Proof of delivery

The plaintiff attached a copy of the above-mentioned guideline to one of its requests for review. (T.752). The ALJ did not hold the plaintiff to a standard higher than prescribed by law. Rather, the ALJ correctly held that plaintiff had an obligation to produce supplemental documents and comply with precise guidelines which are promulgated by the carriers, who act under the authority of the Secretary. The plaintiff misinterpreted, or ignored, the guidelines pertaining to subpart (3), requiring "clinical information in the patient's medical records." The plaintiff consistently produced a copy of a physician's note on a prescription pad stating that a nebulizer was required, along with a copy of a dated physician order, but failed to provide clinical information from the patient's medical record. (T. 55). According to the Region C Spring 2001 DMERC Medical Advisory, "neither a physician's order nor a supplier-prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity even though it is signed by the treating physician." (Id.) This court agrees with the ALJ's findings that "requirements for establishing medical necessity indicated above clearly state that all medical records for the dates of service listed would be required." (T. 55-56). The clinical information from patient's records allows the carriers who evaluate reimbursement of Medicare supplies to assess the validity and necessity of the equipment ordered by the physician.

The plaintiff ignored the requirement of clinical information, submitting only a physician's order and physician attestation. (T. 752) The ALJ gave adequate consideration to the record when she wrote in the decision, "in each case the supplier submitted of physician's orders and copy of physician's prescription for the medications. . . [this is] not sufficient to establish medical necessity. The establishment of medical necessity in this instance was very document specific and the documentation was not there." (T. 55-56).

The ALJ's holding that plaintiff failed to comply with the precise requirements provided in the guidelines is further illustrated by documents in the record. For beneficiary Ana Castro, the Plaintiff completed a DMERC Review Request Form, dated September 23, 2002. (T. 752). On the Review Request form, the supplier referenced the requirements for an additional development claim, *supra*, attaching one page of the 2001 Spring DMERC Medicare Advisory, with the form. (Id.). The plaintiff wrote on the Review form, "See attached copy of the advisory pointing out that a supplier prepared statement or physician's attestation (certification) may be submitted to justify medical necessity ***in lieu of medical records***." (Emphasis added) (T. 751-752). In fact, the Advisory does not state that certain documents can be submitted in lieu of medical records. Rather, following the requirement of clinical information, the guideline continues, "It ***may also include*** information on a supplier-prepared statement or physician attestation (if applicable)." (Emphasis added). (Tr. 751). As the ALJ aptly noted in her decision, this case turns on specific language in the Medicare Advisories. (T.55) Where claims have been identified as additional development requests, the supplier must produce clinical information from the patients records to warrant a finding of medical necessity. The Medicare Advisories are specific in requiring clinical information in the patient's medical records. Merely providing physician's orders and physician attestations alone have been rejected by the carriers, as provided

in the Region C Spring 2001 DMERC Medicare Advisory. Accordingly, the ALJ determined that plaintiff had failed to comply under the Medicare Act. (T.55).

This court must give substantial deference to an agency's interpretation of its own regulations. *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 150-151, 111 S.Ct. 1171, 1175-1176, 113 L.Ed.2d 117 (1991); *Lyng v. Payne*, 476 U.S. 926, 939, 106 S.Ct. 2333, 2341, 90 L.Ed.2d 921 (1986). This broad deference is all the more warranted when, as here, the regulation concerns a 'complex and highly technical regulatory program.' *Thomas Jefferson v. Shalala*, 512 U.S. 504, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994), (quoting *Pauley v. BethEnergy Mines, Inc*., 501 U.S. 680, 697, 111 S.Ct. 2524, 2534, 115 L.Ed.2d 604 (1991). The agency's interpretation must be given "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id.* (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414, 65 S.ct. 1215, 1217, 89 L.Ed. 1700 (1945)).

In addition to plaintiff's failure to fully comply with the medical records requirement, the ALJ held plaintiff failed to produce manufacturer information. (T. 55). The Medicare Advisory requires manufacturer information for claims identified for additional development. (T. 751). The plaintiff failed to show that this information had been produced to the carrier, as required by the Medicare Advisory. To justify its failure to produce manufacturer information, the plaintiff wrote in its brief, "[m]anufacturer's information provides no information that supports medical necessity." (Plaintiff's Brief at p.5). Typically, manufacturer's information is not required. However, when claims are identified for additional development, supplemental documents are requested to prove medical necessity. (T. 55, 751). Not every claim is identified as an additional development claim. When the carrier notes the over-use of certain equipment codes, the supplier is put on notice that supplemental documentation will be required to warrant medical necessity

and, therefore, justify reimbursement for said equipment. The aforementioned provisions are intended to prevent fraud and misuse of public funds distributed pursuant to the Medicare Act. The plaintiff supplier is aware of the supplemental documentation, and in fact, attached a copy of the additional development requirements with beneficiary Ana Castro's Review Request Forms when appealing the denial of reimbursement to the carrier. (T. 751). In the absence of requested documentation, including manufacturer information, the claims are determined to not be medically necessary. This court defers to the guidelines drafted by the Secretary and the interpretation of the guidelines by the Secretary, and concurs in the ALJ's holding that in claims identified for additional development, manufacturer information is a reasonable request by the carrier. (T. 55).

The ALJ's finding that plaintiff failed to meet the requirements of medical necessity, as required for an additional development claim, is more than supported by the record and applicable law.

B. <u>Substantial Evidence</u>

Substantial evidence is evidence that a reasonable mind would accept as adequate to support the decision. *Austin v. Shalala*, 994 F.2d 1170, 1174 (5th Cir. 1993), citing *Richardson v. Perales*, 402 U.S. 389, 401, 91 S.ct. 1420, 1427, 28 L.Ed.2d 842 (1971). Where substantial evidence supports the administrative finding, the court may then only review whether the ALJ applied the proper legal standards and conducted the proceedings in conformity with the applicable statutes and regulations. *Hernandez v. Heckler*, 704 F.2d 857, 859 (5th Cir. 1983). Of course, this standard of review is not a rubber stamp for the Secretary's decision. It involves more than a basic search for evidence supporting the findings of the Secretary. The court must scrutinize the record and take into account whatever fairly detracts from the substantiality of

evidence supporting said findings. *Austin v. Shalala*, 994 F.2d at 1174, *citing Tome v. Schweiker*, 724 F.2d 711, 713 (8th Cir. 1984).

The record in this case establishes no doubt that the plaintiff submitted a portion of the documentation as required by the Medicare Advisory. However, plaintiff is not entitled to reimbursement unless all of the information requested by the regional carriers is provided, pursuant to § 1833(e) of the Social Security Act, 42 U.S.C. § 13951 (e). The ALJ's ruling that plaintiff failed to produce sufficient documentation is supported by substantial evidence. That plaintiff failed to provide documents adequate to prove medical necessity, under an additional development plan, is supported by substantial evidence in the record without relying on defendant's exhibits 4 and 5, which are not part of the administrative record. This court considers the exhibits only to the extent that their content further illuminates information in the record, and further illustrates that the ALJ considered relevant factors in the determination of medical necessity. *Citizens to Preserve Overton Park v. Volpe*, 401U.S. 402, (1971); *Camp v. Pitts*, 411 U.S. 138 (1973); *Asarco, Inc. v. U.S.E.P.A.*, 616 F.2d 1153, 1160 (9th Cir. 1980); *Bunker Hill Co v. EPA*, 572 F.2d 1286, 1292 (9th Cir. 1977).

On May 21, 2002, the carrier made specific requests to the provider for documents, "especially the medical chart progress notes of the physician or health care provider . . . which refer to or describe the medical condition and treatment plans relating to the billed item." (Ex. 4 to Defendant's Brief). Additionally, it specifically requested manufacturer information in the May 21, 2002, letter. On October 8, 2002, the carrier advised plaintiff that it was being placed on a provider-specific review due to its failure to comply with document requests, and again requested specific and precise information from the patient's medical records. (Ex. 5 to Defendant's Brief). In the October letter, the plaintiff was referred to the 2001 Spring Advisory

which stated, "the patient's medical records must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered. . ." (2001 Spring Medicare Advisory at p. 16.). The ALJ's finding that submitting a physician's order and a physician attestation, by itself, are insufficient documentation to meet the requirements of medical necessity for an additional development claim should not be disturbed, is not contrary to the law, and is supported by substantial evidence. The carrier made legitimate requests as provided by the Medicare Advisories. The sufficiency of documentation is a fact-intensive inquiry, and this court will not disturb the ALJ's holding unless clearly erroneous.

Reviewing the record as a whole, the court finds that the ALJ was not clearly in error in concluding that the plaintiff was not entitled to reimbursement under sections 42 U.S.C.§ 1395j-1395w and 42. U.S.C. § 1395u respectively, of the Medicare Act. This court is satisfied that the ALJ gave adequate consideration to the record, and, further, the ALJ decision was supported by substantial evidence.

This court agrees with the ALJ's holding that plaintiff failed to comply with the requirements of an additional development claim**.** (T. 55-56) The supplemental documentation may be viewed as a burden to the plaintiff supplier, however, in an effort to prevent fraud and abuse of funds distributed under the Medicare Act, the carrier is justified in requiring supplemental documentation for claims identified for additional development.

The parties are referred to 28 U.S.C. §636(b)(1)(B) and FED. R. CIV. P. 72(b) for the appropriate procedure in the event any party desires to file objections to these findings and recommendations. Objections are required to be in writing and must be filed within ten (10) days of this date and "a party's failure to file written objections to the proposed findings, conclusions, and recommendation in a magistrate judge's report and recommendation within 10 days after

being served with a copy shall bar that party, except upon grounds of plain error, from attacking on appeal the unobjected-to proposed factual findings and legal conclusions accepted by the district court . . . ." *Douglass v. United Services Automobile Association*, 79 F.3d 1415, 1428-29 (5th Cir. 1996) (*en banc*) (citations omitted).

Respectfully submitted.

THIS, the 1st day of August, 2005.

/s/ S. Allan Alexander

UNITED STATES MAGISTRATE JUDGE